



## Medical School Hotline

### Commitment to "Diversity"

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For twenty-five years, the University of Hawaii John A. Burns School of Medicine (JABSOM) has successfully conducted an

affirmative-action program known as *Imi Ho'ola* (*Those Who Seek to Heal*). This Program's efforts have contributed to the promotion of diversity within JABSOM's student population by providing opportunities in medicine for Native Hawaiians, Filipinos, Samoans, residents of the US-Affiliated Pacific Islands (Marshallese, Pohnpeians, Kosraeans, Yapese, Chamorros, Palauans) and South-East Asian immigrants. In 25 years, 337 have been accepted into the Program. Seventy-four percent or 123 students have graduated from JABSOM. Others have become nurses, public health workers, medical technologists and other health specialties.

A primary feature of the Program is to train physicians who will serve the socially, economically, and educationally disadvantaged populations. There is a desperate need for physicians who identify themselves with these populations to deliver culturally competent

and effective health care. This is not only evident in the Pacific but in our entire nation. At the 1996 Annual Meeting of the Association of American Medical Colleges (AAMC), Dr Jordan J. Cohen, President of the AAMC, stated, "Learning how to deliver culturally competent care means learning medicine ... from faculty who are themselves emblematic of society's diversity. Textbooks alone just won't cut it" (1996, p 4). A sequel to this goal is the development of physician leaders who will not only contribute to the total welfare of the community in which they find themselves, but become teachers in medicine.

Graduates have also returned to serve as faculty at JABSOM. They teach in the classrooms as well as in the community hospitals and clinics. Imi Ho'ola graduates comprise 2 percent of the compensated faculty at JABSOM. Two graduates from *Imi Ho'ola* are Chairpersons for the Department of Psychiatry and the Department of Family Practice and Community Medicine. In addition, *Imi Ho'ola* alumni participate in recruitment activities at the high school and university levels for students who will augment their numbers as well as replace them in the vital role of serving those least represented ethnic groups in Hawaii. As physicians, these graduates serve as role models to those who have an exceptional desire and motivation toward a medical career. An example is Dr Phillip Reyes, the Co-Medical Director for the Molokai General Hospital. Born and raised on the island of Molokai, Dr Reyes provides needed primary care services to the people of Molokai. In addition, he works in partnership with the schools in promoting health careers among the youth.

## AZELEX<sup>®</sup>

(AZELAIC ACID CREAM) 20%

For Dermatologic Use Only Not for Ophthalmic Use

**DESCRIPTION:** AZELEX<sup>®</sup> (azelaic acid cream) 20% contains azelaic acid, a naturally occurring saturated dicarboxylic acid. Structural Formula: HOOC-(CH<sub>2</sub>)<sub>7</sub>-COOH. Chemical Name: 1,7-heptanedicarboxylic acid. Empirical Formula: C<sub>9</sub>H<sub>16</sub>O<sub>4</sub>. Molecular Weight: 188.22. **Active Ingredient:** Each gram of AZELEX<sup>®</sup> contains azelaic acid 0.2 gm (20% w/w). **Inactive Ingredients:** cetylalcohol, glycerin, glyceryl stearate and cetylalcohol and cetyl palmitate and cocoglycerides, PEG-5 glyceryl stearate, propylene glycol and purified water. Benzoic acid is present as a preservative. **CLINICAL PHARMACOLOGY:** The exact mechanism of action of azelaic acid is not known. The following *in vitro* data are available, but their clinical significance is unknown. Azelaic acid has been shown to possess antimicrobial activity against *Propionibacterium acnes* and *Staphylococcus epidermidis*. The antimicrobial action may be attributable to inhibition of microbial cellular protein synthesis. A normalization of keratinization leading to an anticomonal effect of azelaic acid may also contribute to its clinical activity. Electron microscopic and immunohistochemical evaluation of skin biopsies from human subjects treated with AZELEX<sup>®</sup> demonstrated a reduction in the thickness of the stratum corneum, a reduction in number and size of keratohyalin granules, and a reduction in the amount and distribution of filaggrin (a protein component of keratohyalin) in epidermal layers. This is suggestive of the ability to decrease microcomedo formation. **Pharmacokinetics:** Following a single application of AZELEX<sup>®</sup> to human skin *in vitro*, azelaic acid penetrates into the stratum corneum (approximately 3 to 5% of the applied dose) and other viable skin layers (up to 10% of the dose is found in the epidermis and dermis). Negligible cutaneous metabolism occurs after topical application. Approximately 4% of the topically applied azelaic acid is systemically absorbed. Azelaic acid is mainly excreted unchanged in the urine but undergoes some  $\beta$ -oxidation to shorter chain dicarboxylic acids. The observed half-lives in healthy subjects are approximately 45 minutes after oral dosing and 12 hours after topical dosing, indicating percutaneous absorption rate-limited kinetics. Azelaic acid is a dietary constituent (whole grain cereals and animal products), and can be formed endogenously from longer-chain dicarboxylic acids, metabolism of oleic acid, and  $\alpha$ -oxidation of monocarboxylic acids. Endogenous plasma concentration (20 to 80 ng/mL) and daily urinary excretion (4 to 28 mg) of azelaic acid are highly dependent on dietary intake. After topical treatment with AZELEX<sup>®</sup> in humans, plasma concentration and urinary excretion of azelaic acid are not significantly different from baseline levels. **INDICATIONS AND USAGE:** AZELEX<sup>®</sup> is indicated for the topical treatment of mild-to-moderate inflammatory acne vulgaris. **CONTRAINDICATIONS:** AZELEX<sup>®</sup> is contraindicated in individuals who have shown hypersensitivity to any of its components. **WARNINGS:** AZELEX<sup>®</sup> is for dermatologic use only and not for ophthalmic use. There have been isolated reports of hypopigmentation after use of azelaic acid. Since azelaic acid has not been well studied in patients with dark complexions, these patients should be monitored for early signs of hypopigmentation. **PRECAUTIONS: General:** If sensitivity or severe irritation develop with the use of AZELEX<sup>®</sup>, treatment should be discontinued and appropriate therapy instituted. **Information for patients:** Patients should be told: 1. To use AZELEX<sup>®</sup> for the full prescribed treatment period. 2. To avoid the use of occlusive dressings or wrappings. 3. To keep AZELEX<sup>®</sup> away from the mouth, eyes and other mucous membranes. If it does come in contact with the eyes, they should wash their eyes with large amounts of water and consult a physician if eye irritation persists. 4. If they have dark complexions, to report abnormal changes in skin color to their physician. 5. Due in part to the low pH of azelaic acid, temporary skin irritation (pruritus, burning, or stinging) may occur when AZELEX<sup>®</sup> is applied to broken or inflamed skin, usually at the start of treatment. However, this irritation commonly subsides if treatment is continued. If it continues, AZELEX<sup>®</sup> should be applied only once-a-day, or the treatment should be stopped until these effects have subsided. If troublesome irritation persists, use should be discontinued, and patients should consult their physician. (See ADVERSE REACTIONS.) **Carcinogenesis, mutagenesis, impairment of fertility:** Azelaic acid is a human dietary component of a simple molecular structure that does not suggest carcinogenic potential, and it does not belong to a class of drugs for which there is a concern about carcinogenicity. Therefore, animal studies to evaluate carcinogenic potential with AZELEX<sup>®</sup> Cream were not deemed necessary. In a battery of tests (Ames assay, HGPRT test in Chinese hamster ovary cells, human lymphocyte test, dominant lethal assay in mice), azelaic acid was found to be nonmutagenic. Animal studies have shown no adverse effects on fertility. **Pregnancy: Teratogenic Effects: Pregnancy Category B.** Embryotoxic effects were observed in Segment I and Segment II oral studies with rats receiving 2500 mg/kg/day of azelaic acid. Similar effects were observed in Segment II studies in rabbits given 150 to 500 mg/kg/day and in monkeys given 500 mg/kg/day. The doses at which these effects were noted were all within toxic dose ranges for the dams. No teratogenic effects were observed. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. **Nursing Mothers:** Equilibrium dialysis was used to assess human milk partitioning *in vitro*. At an azelaic acid concentration of 25  $\mu$ g/mL, the milk/plasma distribution coefficient was 0.7 and the milk/buffer distribution was 1.0, indicating that passage of drug into maternal milk may occur. Since less than 4% of a topically applied dose is systemically absorbed, the uptake of azelaic acid into maternal milk is not expected to cause a significant change from baseline azelaic acid levels in the milk. However, caution should be exercised when AZELEX<sup>®</sup> is administered to a nursing mother. **Pediatric Use:** Safety and effectiveness in pediatric patients under 12 years of age have not been established. **ADVERSE REACTIONS:** During U.S. clinical trials with AZELEX<sup>®</sup>, adverse reactions were generally mild and transient in nature. The most common adverse reactions occurring in approximately 1-5% of patients were pruritus, burning, stinging and tingling. Other adverse reactions such as erythema, dryness, rash, peeling, irritation, dermatitis, and contact dermatitis were reported in less than 1% of subjects. There is the potential for experiencing allergic reactions with use of AZELEX<sup>®</sup>. In patients using azelaic acid formulations, the following additional adverse experiences have been reported rarely: worsening of asthma, vitiligo depigmentation, small depigmented spots, hypertrichosis, reddening (signs of keratosis pilaris), and exacerbation of recurrent herpes labialis. **DOSEAGE AND ADMINISTRATION:** After the skin is thoroughly washed and patted dry, a thin film of AZELEX<sup>®</sup> should be gently but thoroughly massaged into the affected areas twice daily, in the morning and evening. The hands should be washed following application. The duration of use of AZELEX<sup>®</sup> can vary from person to person and depends on the severity of the acne. Improvement of the condition occurs in the majority of patients with inflammatory lesions within four weeks. **HOW SUPPLIED:** AZELEX<sup>®</sup> is supplied in collapsible tubes in a 30 gm size: 30 g - NDC 0023-8694-30. **Note:** Protect from freezing. Store between 15°-30°C (59°-86°F). **Caution:** Federal (U.S.A.) law prohibits dispensing without a prescription. Distributed under license; U.S. Patent No. 4,386,104.

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Finally, the Program is mindful that it must not lose sight of the need to recognize their most important resource and responsibility, the community which the graduates serve. Currently, sixty-two percent of the *Imi Ho'ola* graduates are practicing in rural areas of Oahu and the Neighbor Islands. To ensure the relationship with the community, a community advisory committee has functioned since the inception of the Program in 1973 to guide the Program. Committee members include lawyers, psychologists, bankers, teachers and graduates of the program.

*Imi Ho'ola* is fulfilling the mission of the John A. Burns School of Medicine by teaching and training high quality physicians for Hawaii and the Pacific, thereby promoting diversity in the medical profession.

#### Reference

1. Cohen, Jordan J. *Finishing the Bridge to Diversity*. Washington, DC: Association of American Medical Colleges. 1996:4.

## Public Service Announcements

**American Cancer Society Seeking Volunteers.**—Volunteers with medical knowledge needed to staff and man the library and a call-in telephone information line. These people will be trained by the American Cancer Society, and will be responsible for giving out cancer information to walk-ins and callers. For further information call Susan Jacobs at the American Cancer Society, 595-7500 ext. 202.

Volunteers needed for Angels on Wheels, drivers to take cancer patients to and from their doctor/cancer therapy appointments. To volunteer, contact the American Cancer Society office in your area.

Volunteers needed at all American Cancer Society offices to assist in clerical duties. Call to volunteer: Windward 262-5124, Leeward 486-8404, and Honolulu 595-7544.

**Seeking Helpline Volunteers.**—The Honolulu Chapter of the Alzheimer's Assn. is seeking caring individuals to provide information and referrals and emotional support to callers needing assistance in coping with Alzheimer's disease. Volunteers will answer the telephone Helpline a minimum of 3-4 hours a week at our friendly Honolulu chapter office, Monday-Friday, between the hours of 9 and 4 p.m. Orientation and training will be provided. For further information or to receive a volunteer application, please contact the Honolulu Chapter at 591-2771.

**Hospice Hawaii Volunteer Training.**—20-hr course at Hospice Hawaii office. Wednesday, Sept. 9, 6-9 p.m.; Saturday, Sept. 12, 8-5 p.m.; Saturday, Sept. 19, 8-5 pm. Call 924-9255, ext. 219 for more information.

**Music Therapy Lectures Aug. 22.**—Open to the public, held at Hospice Hawaii office, call Barb Shirland, 924-9255 ext. 209. Featuring: Dr. Deforia Lane and Daniel Kobiaka. The Music Therapy Program involves both listening and participation and provides benefits in many areas including: physical, psychological, social and spiritual. Founded in 1979, Hospice Hawaii is a non-profit organization that offers medical, social, emotional, and spiritual support for patients and families facing a terminal illness.



## President's Message

### Managed Care Concerns

**Leonard Howard MD**  
President, Hawaii Medical Association

There are many advantages for the physician to participate in the various managed care entities in our state. However, there are also some problems at the root of all managed care participation. The problems present themselves in subtle ways, that are sometimes not recognized as problems by physicians. These problems are the result of various Sections and Provisions of the Participating Provider Agreement that is signed in order to participate in a managed care organization (MCO).

Time and time again in reviewing MCO contracts the same land mines are found present in the contracts. It is necessary that all physicians carefully read the contracts received from an MCO, and understand what commitment is being made by your signature on the contract. There are several common clauses that might be found in a proposed agreement which are likely to cause trouble in various ways. When these clauses are identified in managed care agreements, consider asking whether the subject matter contained in these clauses is really necessary to address in the managed care relationship. If not, they need not be in the agreement and should be removed before the agreement is signed. Seven areas of concern that are often found in many contracts which can be problematic include:

1. **General Offsets and Adjustments.** Provider agrees to authorize Company to deduct moneys that may otherwise be due and payable to Provider from any outstanding moneys that Provider may, for any reason, owe to Company. Provider agrees that Company may make retroactive adjustments to the payment schedule outlined in the agreement. *This provision gives the MCO a free hand to do whatever accounting it desires and deduct moneys from a physician or physician group in its sole discretion without a requirement to account to the physician or physician group and explain such deductions.*
2. **Litigation.** In the event of any litigation between the parties arising out of or related to this Agreement, the prevailing party shall be entitled to recover from the other party its reasonable attorney's fees and cost of litigation, including, without limitation, any expert witness fees. *This clause seems designed to appeal to the unsophisticated physician who abhors litigation and has not stopped to consider that he or she is already greatly disadvantaged in any potential controversy with the company, since the MCO has far more to spend in legal fees. This clause would simply up the ante by potentially doubling (at least) a physician's cost and further chill any prospect for the physician to obtain relief in a court of law.*
3. **Noninterference with Members.** During the term of this Agreement, Provider and its Qualified Physician shall not advise or counsel an Enrollee to dis-enroll from Company's Plan and will not directly or indirectly solicit any Enrollee to enroll in any other MCO or similar Health care service plan or insurance program. *No matter how it is dressed up, provisions*